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K014172

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

## Nelson deluxe Electrosurgical Unit

December 18, 2001

**COMPANY:** Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

**CONTACT:** Lisa M. Millington, Regulatory Associate
800-258-1946 (phone)
610-231-3713 (fax)
lisa.millington@aesculap.com (email)

**TRADE NAME:** Nelson deluxe Electrosurgical Unit

**COMMON NAME:** Monopolar / Bipolar Coagulator, Electrosurgical Unit

**DEVICE CLASS:** Class II

**PRODUCT CODE:** 79 GEI

**CLASSIFICATION:** 878.4400 – Electrosurgical Cutting & Coagulation Device & Accessories

**REVIEW PANEL:** General & Plastic Surgery

**INTENDED USE**

**Aesculap's Nelson deluxe Electrosurgical is intended to be used in surgery to generate electrical power for both Monopolar and Bipolar cutting and coagulating in microsurgery and macrosurgery.**

**DEVICE DESCRIPTION**

Aesculap's **Nelson deluxe Electrosurgical Unit** is an Electrosurgical unit (ESU) capable of generating high frequency electrical current, driven through a software based program, for use in monopolar and bipolar electrosurgery. The Nelson deluxe Electrosurgical Unit is equipped with two monopolar and two biopolar outlets. All software and electrical components are housed within a combination metallic and thermoplastic enclosure and the product is provided with a universal power cord, which automatically adapts to voltages ranging from 100-240 volts. A monopolar or bipolar cord connects the instruments to the coagulator. The unit is activated by means of a foot control or hand piece.

**PERFORMANCE DATA**

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new Nelson deluxe Electrosurgical Unit conforms to applicable IEC standards and the requirements of the Canadian Standards Association (CSA), for medical electrical equipment.

**SUBSTANTIAL EQUIVALENCE**

The Nelson deluxe Electrosurgical Unit described in this premarket notification share similar features and functions such as intended use, labeling, and basic operating principles to the following predicate devices: Conmed / Aspen Laboratories' System 7500 ABC Electrosurgical Unit (#K981220), Erbe's Erbotom ICC 300 & 350 (#K953738 & #K933002), and ValleyLab's Force FX (#K944602).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Lisa Millington
Regulatory Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

K014172
Trade/Device Name: Nelson Electrosurgical Unit, Model GN640
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation
Device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 18, 2001
Received: December 20, 2001

Dear Ms. Millington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

**510(k) Number** (if known): K014172

**Device Name:** **Nelson deluxe Electrosurgical Unit.**

**Indication for Use:**

**Aesculap's Nelson deluxe Electrosurgical is intended to be used in surgery to generate electrical power for both Monopolar and Bipolar cutting and coagulating in microsurgery and macrosurgery.**

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014172

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)